U.S. ENVIRONMENTAL PROTECTION AGENCY
ASSISTANT ADMINISTRATOR MICHAL FREEDHOFF

MEMORANDUM FOR AWARENESS

Date of Briefing: Thursday, July 8, 2021

TOPICS FOR DISCUSSION

- As EPA proceeds through the four-step registration review process for 726 cases and more than 1,100 pesticide active ingredients, OPP has ready six Federal Register Notices (FRNs) announcing the availability of several documents for public comment.
- The documents include preliminary work plans (PWPs), draft risk assessments (DRAs), proposed interim decisions (PIDs) and interim decisions (IDs). Abstracts and summaries of each are presented below. The abstract provides more detail than the summary to reflect higher risks of concern and increased risk mitigation.
- Unless otherwise noted, no proactive communications are planned for these procedural announcements; EPA will have subject matter experts assist with press inquiries should they come in.
- OPP seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development of risk assessments and risk management decisions under registration review. As a part of every pesticide risk assessment, OPP estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns compiled by the USDA are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Whenever appropriate, non-dietary exposures based on occupational and home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Risk management decisions consider any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to pesticides as compared to the general population.

Q2 FY21 REGISTRATION REVIEW FRNs

(**Black** = Abstract, Black = Summary)

FRN #1, FRL 10025-06: Interim Decision for **Paraquat Dichloride** (OCSPP IO briefing May 18, 2021)

FRN #2, FRL 10025-37: Draft Risk Assessment for **Dicamba** (OCSPP IO discussion May 25, 2021)

FRN #3, FRL TBD (Not submitted yet): Preliminary Work Plans for Round 2 of Registration Review

Antimicrobials:	None
Conventionals:	AITC
Biopesticides:	None

FRN #4, FRL TBD (Not submitted yet): Draft Risk Assessments

Antimicrobials:	Copper 8, **Nabam**
Conventionals:	DCNA, **Triadimefon**
Biopesticides:	None

*Dual use conventional/antimicrobial

FRN #5, FRL TBD (Not submitted yet): Proposed Interim Decisions

Antimicrobials:	none
Conventionals:	**Amitraz**, Difenoconazole, Fenbuconazole, Isoxaflutole, Metaldehyde, **MGK-264**, Mesotrione, **Oxadiazon**, **Oxyfluorfen**, **PBO**, **Pyrethrins**, Tembotrione, Topramezone
Biopesticides:	Cinnamaldehyde, Farnesol and Nerolidol[1], *Nosema locustae*[1], *Ulocladium oudemansii* (U3 Strain)[1]

[1] Combined PWP/PID. Fact sheet or summary in the PID section.

FRN #6, FRL TBD (Not submitted yet): Interim Decisions

Antimicrobials:	Citric Acid**, **Halohydantoins**, OBPA, Polixetonium Chloride (Busan 77)
Conventionals:	Acetochlor, **Coumaphos**, Dimethenamid, Fenamidone, Fenazaquin, Myclobutanil, **Propylene Oxide (PPO)***
Biopesticides:	Insect viruses, *Pseudomonas aureofaciens* (case closure)

*Dual use conventional/antimicrobial
**Dual use biopesticide/antimicrobial

FRN DOCUMENT ABSTRACTS AND SUMMARIES

1. Preliminary Work Plan

The preliminary work plan is the first step in the four-step registration review process. Depending on the volume of comments expected and the nature of the pesticide, OCSPP notices availability of the documents in groups.

A. FY2021 Q3 Conventional Preliminary Work Plan (PWP) Summary:

Allyl Isothiocyanate (AITC) and Oriental Mustard Seed

Release preliminary work plan, scoping document, and problem formulation to open the registration review docket for allyl isothiocyanate (AITC) and Oriental mustard seed. Both synthetic AITC and oriental mustard seed were initially classified as biochemical pesticides but have been recently reclassified as conventional pesticides. Synthetic AITC is a broad spectrum non-selective fumigant with fungicidal, herbicidal, insecticidal and nematocidal properties registered for various fruits and vegetables, ornamentals, forest trees and turf. Synthetic AITC is both a restricted and non-restricted use pesticide. Oriental mustard seed, which releases AITC when ground and mixed with water, is a nematicide and insecticide registered as a pre-plant soil treatment for various fruits and vegetables, ornamentals and turf. Oriental mustard seed is a non-restricted use pesticide. HED anticipates conducting toxicological, residue chemistry, and occupational/residential assessments. EFED anticipates conducting comprehensive updated ecological risk assessments, including for pollinators. *Anticipated stakeholder reaction:* Moderate stakeholder feedback is expected due to all the studies that will be called in.

2. Draft Human Health/Ecological Risk Assessments

The draft human health and ecological risk assessments are the second step in the four-step registration review process. Depending on the volume of comments expected and the nature of the pesticide, OCSPP notices availability of the documents in groups. The next step in the process is to propose an interim decision (PID) to mitigate the risks identified.

A. FY2021 Q3 AD (Antimicrobial Use) Draft Human Health and/or Ecological Risk Assessment Abstract and Summary

Nabam DRA Abstract

Current Status

- Nabam is a member of the ethylene bisdithiocarbamate (EBDC) group of chemicals, along with the conventional chemical mancozeb currently undergoing registration review, which are metabolized to ETU (ethylene thiourea) in the body and in the environment.
- There is one end-use product from one registrant registered for use as a bactericide, fungicide, and slimicide in beet sugar and cane sugar mills.
- Target signature date: May 17, 2021

Key Points

- The DCI was issued in August 2019. None of the information required to be submitted as part of this DCI have been submitted. Although some studies are overdue, the residue chemistry studies are not due until August 2021.
    - The registrant has not provided any progress report or indication that data will be submitted.
    - AD has reached out to the registrant on several occasions, but AD has not received a response on how the registrant plans to satisfy the DCI.
- The registrant did not submit any required DCI data; therefore, a conservative analysis was completed using dietary screening level assessments with the maximum labeled concentration. This assessment assumed all the crop (sugar) was treated, no adjustment factors from processing, 100% exposure to a mixture of nabam and ETU, and all toxicity was attributed to the most sensitive compound (ETU) for exposure durations.
- No aggregate risk assessment was completed since nabam dietary risk assessment shows risk for both dietary and drinking water scenarios on their own.

Human Health Risk Assessment Conclusions

- The highly conservative dietary risk assessment indicated acute and chronic risks of concern to all population subgroups except for acute dietary exposure to finished sugar in the female 13-49 subpopulation. Back-calculated concentrations of nabam and ETU in sugar products would need to be <0.38 ppm (87.3% reduction in the maximum application rate of 3ppm results in no risks of concern).
- Similarly, to achieve no drinking water risk to any population subgroup, the combined concentration in sugar mill wastewater would need to be <0.9 ppm (70% reduction) for acute exposure scenario and <0.013 ppm (99.6% reduction) for chronic exposure scenario.
- A cancer dietary assessment was performed for nabam use because ETU is classified as a group B2 (probably human) carcinogen. The cancer risk estimate from exposure to sugar products is 9×10^{-5} and the cancer risk estimate from exposure to drinking water is 4×10^{-3}.
- There are no residential uses of nabam. The occupational exposures and risks to nabam are expected to be minimal based on the label restrictions of closed systems and prohibition of open pouring.

Ecological Risk Assessment Conclusions

- The use pattern of nabam (slimicide in sugar processing) is expected to result in negligible exposure to terrestrial organisms; however, potential exposure to aquatic organisms may occur when the sugar processing water is released into the environment.
- Aquatic acute risks from nabam exist for freshwater and estuarine/marine organisms.
- Acute risks are not of concern for ETU; however, there may be chronic risks to freshwater invertebrates.
- Due to a lack of information on the degradation and dissipation of nabam in sugar processing mills, the makeup of the mixture of nabam, EBIS, ETU, and other degradates within the effluent cannot be determined, and the level of overestimation within the nabam/EBIS calculations cannot be quantified. The required environmental fate data due August 2020 would help refine the risk.
- Acute and chronic risks to freshwater and estuarine/marine organisms and aquatic plants from the use of nabam in sugar mills cannot be precluded and are therefore assumed.

Communications

- No planned communications at this time.

Copper 8-Quinolinolate Summary

Release human health and ecological risk assessment. Copper 8-Quinolinolate is registered for use as a wood preservative for control of sapstain, mold and decay in unfinished wood and wood products such as millwork, decks, outdoor furniture, shingles, structural lumber, boats, mushroom trays and vegetable stakes. The chemical is also registered for use as a disinfectant to control potato ring rot in planters, seed handling equipment and storage areas and for use in the manufacture of kraft paper, paperboard, backerboard and adhesives as well as a materials preservative in industrial military non-apparel textiles (non-aquatic uses only). Although the DRA for copper 8-quinolinolate is still under development, preliminary risk conclusions for human health indicate no risk of concern for chronic dietary exposure, no residential handler or post handler risk of concern, and no occupational handler risk of concern. For the ecological risk assessment, the use patterns of copper 8-quinolinate are expected to result in negligible exposure to terrestrial organisms; however, there is potential for exposures to aquatic organisms from the currently registered uses. Preliminary conclusions indicate a potential for risks to all aquatic taxa from certain uses of copper 8-quinolinate, including material preservation of paper products. *Anticipated Stakeholder Reaction:* TBD.

B. FY2021 Q3 PRD (Conventional Use) Draft Human Health and/or Ecological Risk Assessment Abstracts and Summaries

Dicamba DRA Abstract

Background

- Dicamba is a selective systemic herbicide registered for agricultural and non-agricultural uses.
- Currently there are nine AIs in the dicamba case, three of which do not have any active registrations. There are 552 FIFRA Section 3 registrations and 51 FIFRA Section 24(c) registrations.
- Non-Agricultural sites include agricultural premises, commercial and residential turf, cut stump treatment, forestry, golf courses, garden/ornamentals, outdoor industrial areas, rights of ways, recreational and residential lawns, residential areas.
- Agricultural sites include fallow, conservation reserve, uncultivated land, asparagus, barley, corn, cotton, hay, grass grown for seed, oats, pastures/rangelands, proso millet, small grains, sorghum, soybeans, sugarcane, triticale, wheat.
- Over the top (OTT) uses on dicamba-tolerant GMO soybean and cotton were first registered in 2016 on a two-year time limited registration. Registration was revisited in 2018 which was subsequently vacated by the 9th Circuit in 2020.
- The most recent OTT assessment and decision was in October 2020 which is currently in litigation. The litigation is challenging the 2020 dicamba decision as both too restrictive and too lax.
- Target signature date for ecological and human health DRAs is June 2021.

Key Points

- OCSPP IO discussion May 25, 2021.
- There are no dietary, residential, aggregate, or post-application risks of concern. A few occupational handler scenarios are of concern with current labeling but are addressed by requiring PF10 respirators. One scenario (mixing/loading dry flowable formulations for aerial applications to high acreage field crops) was of concern both with the addition of a PF10 respirator and with consideration of engineering controls.
- There are ecological risks of concern identified for birds, mammals, honeybees, and non-target terrestrial plants. There have been thousands of non-target plant ecological incidents with a steep increase in incidents since 2015 with the registration of over the top (OTT) uses as the timing of OTT applications later in the season leads to greater risk of volatilization.
- The OCSPP IO has been briefed by RD on the dicamba OTT registration and litigation in February 2021.
- Historically dicamba is important to growers of corn, fallow, pasture, sorghum, soybeans, sugarcane, and wheat crops. With the addition of OTT uses on cotton and soybeans the dicamba use on these crops is likely increasing.

Human Health Risk Assessment Conclusions

- The human health database for dicamba is complete. No additional data are required, nor are additional updates needed at this time. The endpoints, doses, and safety factors reflect current HED practices and policies for hazard evaluation.
- There are no acute or chronic dietary risks of concern for the U.S. population or any population subgroup.
- There are no residential handler and post-application risks of concern (only inhalation and incidental oral assessed; no potential hazard via the dermal route identified).
- No spray drift risks of concern for adults or children 1<2 years old.
- Bystander volatilization: PERFUM modeling indicates that airborne concentrations, even at the edge of the treated fields, are negligible, and risk estimates are not of concern.
- Occupational handler:
    - Most scenarios are not of concern (*i.e.*, MOEs ≥ the LOC of 30) with no respirator (a respirator is currently not required on product labels).
    - Some scenarios are of concern without a respirator (*e.g.*, mixing/loading dry flowables for application to sod and agricultural crops), but these are not of concern with the addition of a PF10 respirator.
    - One scenario (mixing/loading dry flowable formulations for aerial applications to high acreage field crops) was of concern both with the addition of a PF10 respirator and with consideration of engineering controls. Reducing the application rate addresses the concern, but the team needs to investigate further.
- Occupational post-application: quantitative assessment not conducted since no dermal hazard identified.

Ecological Risk Assessment Conclusions

- Past assessments covering a range of use patterns and application rates identified potential acute and chronic risk to birds, chronic risk to mammals, chronic risk to bees (larvae), aquatic plants and non-target terrestrial plants.
- Consistent with the previous assessments, the environmental fate and effects data used in this assessment are bridged across the dicamba acid and all the supported dicamba salts.
- Numerous non-target plant incidents reported with an exponential increase in the number reported since the 2016 registration of the OTT uses on dicamba-tolerant GE soybean and cotton.
- Based on its environmental fate profile, dicamba is expected to move off-site via runoff, drift, and volatility. Volatility of pre-emergent and post-harvest uses is expected to be lower than OTT uses because temperatures are anticipated to be lower for early season applications compared to later in the season OTT applications.

Communications. OPP update, web update, press statement recommended.

Triadimefon DRA Abstract

Current Status

- Joint conventional/antimicrobial registration review case, however, all registered antimicrobial uses have been cancelled.
- Triadimefon is a triazole-derivative fungicide registered for use in greenhouses, pine seed treatments, tree injections, and for use on turf and ornamentals.
- There are nine FIFRA Section 3 registrations for triadimefon. All registrations for triadimenol, a metabolite of triadimefon, have been cancelled, however, triadimenol retains an import tolerance for bananas.
- There is very little quantifiable usage data available for triadimefon for the last 5 years.
- Target signature date for the ecological and human health DRAs is June 2021.

Key Points

- The Agency rescinded the voluntary cancellation orders for Bayer's triadimefon products in December 2020 based on a registrant's request following data compensation negotiations between registrants Bayer and Chemstarr.
- Acute human health risks of concern are expected from drinking water.

Human Health Risk Assessment Conclusions

- The toxicological endpoints were re-evaluated, and some endpoints were updated. A quantitative dermal assessment is not needed. All endpoints are based on evidence of neurotoxicity.
- Occupational and Residential Exposure (ORE)/Risk Assessment
    - No risk estimates of concern for residential post-application or spray drift
    - Occupational handler: There are two risk exceedances (mixing/loading of DF formulations for aerial and chemigation use on sod) at label-required clothing/PPE
- Dietary Exposure and Risk Assessment
    - The only source of food exposure is from imported bananas.

- There are acute and chronic dietary risk exceedances for the "all infants" subgroup, and these exceedances are driven by drinking water residues.

Ecological Risk Assessment Conclusions

- The primary ecological risks expected are chronic risks to birds and mammals, bees, freshwater fish and aquatic invertebrates, as well as risks to terrestrial plants.
- There were no incidents reported for triadimefon.

Drinking Water Assessment Conclusions

- Estimated Drinking Water Concentrations are above the acute DWLOC for ground water as the residues of concern (triadimefon and triadimenol) are mobile and persistent in the environment. This indicates likely dietary risks of concern when the human health DRA is completed.

Communications: No planned communications

DCNA DRA Summary

Release human health and ecological risk assessments. DCNA is an aromatic hydrocarbon fungicide (FRAC group 14) that can be used pre- and post-harvest on various crops. It has no residential uses. The highest uses in terms of annual pounds applied are lettuce and celery. The highest uses in terms of the percent crop treated are celery and onions. There is currently a voluntary cancelation for uses on geranium and hydrangea pending finalization, and several additional voluntarily cancelled uses awaiting label implementation. Additionally, a Developmental Neurotoxicity Study (DNT) is outstanding and is unlikely to be complete until after the registration review process; in the absence of the study, an FQPA Safety Factor (SF) of 10X has been retained as a database uncertainty factor (UF_{DB}) for dietary and non-occupational assessments. For occupational assessments, a 10X UF_{DB} has been retained pending submission of the DNT. Risks for dietary (food and water) were found to be not of concern for all populations in the acute and chronic assessments. Risks of concern exist via dermal exposure for all populations (and incidental oral for children 1<2 years) for non-occupational spray drift from aerial and groundboom applications. Most occupational exposure scenarios are of concern (LOC = 1000 due to lack of a DNT), often with maximum PPE and/or engineering controls.

In the previous ecological risk assessment, potential risks were indicated for freshwater fish and amphibians on an acute basis; birds and reptiles on an acute and chronic basis; and mammals on a chronic exposure basis. There were no acute risk LOC exceedances for either freshwater or estuarine/marine invertebrates, or mammals. The potential for risks to terrestrial invertebrates and plants, and aquatic plants, is unknown, because these studies are still being reviewed. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is anticipated.

3. Proposed Interim Decisions

The Proposed Interim Decisions (PIDs) are the third step in the four-step process. In the PID, EPA proposes mitigation measures to reduce the human health and ecological risks identified in the draft risk assessments, taking into account public comment. For the most part, no proactive

communications are planned for these procedural announcements. EPA will have subject matter experts assist with press inquiries should they come in.

A. FY2021 Q3 PRD (Conventional Use) PID Abstracts and Summaries

Amitraz PID Abstract

Current Status

- Amitraz is an insecticide and miticide. It is used in dog collars to provide protection from tick species of public health concern and is used by beekeepers as a highly effective miticide to control varroa mites.
- There are only two end use product registrations, neither of which contain other actives:
    - Preventic (EPA Reg. No. 2382-104): a dog collar to control ticks
    - Apivar (EPA Reg. No. 87243-1): impregnated strips to control varroa mites in beehive
- There are amitraz dog shampoos and dips which are regulated under the FDA as veterinary medicines.
- PID scheduled for June 2021.

Key Points

- No human health or ecological risks of concern besides potential honeybee risk from registered Varroa mite use.
- ESA determination of "No Effect" has been made for current amitraz registrations.
- Amitraz tick collars provide months of tick protection on dogs and an additional mode of action when resistance occurs with other active ingredients
- First PID that:
    - Discusses calling in enhanced incident and sales reporting data for pet products, including pet collars.
    - Provides a summary of pet incidents for the a.i.

Human Health Risk Assessment Conclusions

- No human health risks of concern.
- Only one minor human health incident associated with Preventic dog collar and no human health incidents associated with Apivar have been reported to OPP IDS in the past 5 years.

Ecological Risk Assessment Conclusions

- No ecological risks of concern beyond potential risks to honeybees associated with amitraz' registered use in hives to address Varroa mites.
- A "No Effect" determination has been made for all federally listed species based on limited exposure potential to non-target organisms outside of beehives.
- Since 2014, four "possible" honeybee incidents have been reported that are associated with the use of Apivar. Three incidents involved the presence of highly toxic insecticides, and one incident involved the use of an herbicide.

Pet Incidents

- In the last five years, 109 pet incidents were reported to OPP IDS for the Preventic collar, including 2 animal deaths, 3 major severity incidents, and 56 moderate severity, 47 minor severity incidents, and one incident that had no or unknown effects.
- Including a summary of the pet incidents in PID.

Proposed Mitigation in PID
- No mitigation is being proposed.

Oxadiazon PID Abstract

Current Status
- Oxadiazon is a selective pre- and early post-emergence light-dependent peroxidizing herbicide (LDPH) in the oxadiazole class used to control annual grasses and broadleaf weeds.
- Registered for non-agricultural use on turf (*e.g.*, golf course fairways, putting greens and tees, athletic fields, parks, non-residential lawns) and rights-of-way as well as some agricultural use sites (*e.g.*, ornamental beds, sod farms, conifer nurseries). There are no registered food or residential turf uses.
- There are two technical registrants (Bayer and Adama) and 61 FIFRA Section 3 registrations.
- PID scheduled for June 2021.

Key Points
- Greatest usage is on golf course fairways (>75% of total usage). Other turf (<10% of total usage); landscape bedding and rights-of-way (<15% of total usage); and nursery ornamentals including pine seedlings (<5% of total usage) are relatively minor uses.
- High benefits for pre-emergent control of goosegrass and crabgrass in turf; and targeting of weeds in conifer and ornamental (bareroot and container) nurseries without affecting root growth.
- Oxadiazon is prohibited on residential lawns but can be applied to residential gardens and landscaping/ornamentals by professional handlers.
- Applied as granules, granular on fertilizer, wettable powder (water-soluble packets), and flowable concentrate (liquid).
- Golf course fairways are predominant and representative use site at the national level and were used to assess dietary risks from drinking water. Using a modified turf scenario, golf course adjustment factor, and proposed reduced application rates resulted in no dietary risks of concern.
- To resolve post-application residential cancer risks, use cancellations are proposed for other types of turf (non-golf and non-sod farms) and liquid applications to ornamentals.
- Agency has requested additional information from stakeholders on nursery ornamental sites (particularly southern pine seedling nurseries) to determine if localized drinking water mitigation may be needed.

Human Health Risk Assessment Conclusions
- Turf refinements (modified turf scenario, limit to golf course fairways, reduce application rates) resolve dietary risks of concern from drinking water.

- Residential post-application cancer risks remain from liquid applications to gardens and liquid or granular applications to commercial turf (e.g. parks, cemeteries, athletic fields); but not from golf courses.
- Combined cancer risks of concern remain from *drinking water exposure + post-application golfing exposure* if two liquid applications are used on golf courses.
- Occupational handler cancer and non-cancer risk remains for liquid backpack broadcast applications to turf.
- Occupational post-application cancer and non-cancer risk remains from handling irrigation equipment in nurseries; minimum of 4 days REI to pass LOC.
- ORE estimates reflect HED's refinements using typical application rates (3.0 lb ai/A), which reduced cancer risks in multiple scenarios.
- The risk estimates incorporate HED's refinements to the occupational/residential risk assessment related to and focused on typical application rates (*i.e.*, 3.0 lb ai/A), which reduced cancer risk estimates for multiple scenarios (both residential and occupational).

Ecological Risk Assessment Conclusions

- Chronic risks of concern for freshwater and estuarine/marine fish and aquatic invertebrates.
- Risks for concern for vascular and non-vascular aquatic plants and terrestrial plants.
- Chronic risks of concern to birds using upper-bound Kenaga values.
- Chronic risks to terrestrial invertebrates (larval and adult honeybees).

Proposed Mitigation in PID

Human health

- Residential post-application risk mitigations:
  - Prohibit uses on turf except for golf course fairways and sod farms.
  - Prohibit liquid applications to all ornamental, landscaping, and rights-of-way sites except groundboom applications to conifer nurseries.
- Drinking water and combined cancer risk mitigations after refinements:
  - Golf course fairways and sod farms: reduce annual and single maximum application rates (to 3.0 lbs ai/A × 2 applications/year); limit liquid applications to once per year while allowing "blended" liquid/granular applications (must apply liquid prior to any additional granular applications on golf courses).
  - Ornamentals: reduce granular application rate to 3.0 lbs ai/A × 2/year; reduce maximum liquid application rate to 1.9 lbs ai/A/year (conifer nurseries only).
- Occupational handler and post-application risk mitigations:
  - Cancel water-soluble packet (WSP) formulation.
  - Restrict mechanically pressurized handgun (MPHG) applications to golf course fairways only.
  - Restrict liquid backpack applications on turf to spot treatments only (no need for double-layer attire).
  - Increase REI to 4 days for hand-set irrigation activities in ornamental and conifer nurseries.
- *Moderate impacts* expected from turf use cancellations, application rate reductions, and MPHG restrictions.
- *Low impacts* expected from all other mitigations.

Ecological

- Update and standardize environmental hazard statements across labels.
- Mandatory and advisory spray drift language (*i.e.*, droplet size and wind speed restrictions) for liquid formulations.
- Non-target organism advisory statement
- Surface water and groundwater advisory statements

Communications

- Registrants have agreed to application rate reductions, cancellation of water-soluble packet formulation, and cancellation of liquid formulations for ornamentals/nursery sites. Registrants are aware of other mitigation measures and intend to provide comments to the PID.
- No other communication planned.

Oxyfluorfen PID Abstract

Current Status

- Oxyfluorfen is an herbicide first registered in 1979 and is used on a wide variety of crops including forestry, corn, soybeans, grapes, coffee, and bananas, ornamentals. There are some residential use sites. There were 2.6 million pounds applied annually across all crops between 2014-2018. Almonds had the highest percent crop treated with 60% and the most pounds applied with 300,000/year.
- It is a light-dependent peroxidizing herbicide (LDPH) that uses sunlight to activate the toxic mechanism. This mechanism is also active on some non-target species including fish.
- There are 17 registrants and 37 FIFRA Section 3 products and 8 Special Local Need products.
- PID scheduled for June 2021.

Key Points

- Based on current label use patterns, oxyfluorfen is exceeding dietary risks for cancer.
- In order to reduce dietary risk, revocation of import tolerances for bananas will be proposed.
- Occupational and residential application for numerous crops resulted in cancer and non-cancer risks of concern.
- Oxyfluorfen has high benefits for grapes, tree nuts, stone fruits, coffee and cacao, nursery crops, Christmas trees, and forestry, among other uses.

Human Health Risk Assessment Conclusions

- The risk assessment indicates dietary and aggregate cancer risk estimates of concern.
- Non-cancer residential handler risks of concern were not identified.
- The majority of non-cancer occupational handler exposure scenarios are not of concern with additional PPE. Some scenarios, such as mix/load/apply liquid via backpack and mix/load/apply liquid via mechanically pressurized handgun, remain of concern despite additional PPE.

- The majority of occupational post-application non-cancer risks are not of concern on the day of product application. For ornamentals, a 4-day REI is required to reach an MOE not of concern.

Ecological Risk Assessment Conclusions

- Risk of decreased growth for terrestrial and aquatic plants.
- Chronic risks for fish and aquatic invertebrates.
  - Presence of UV light enhances chronic toxicity to fish.
  - There is also risk of mortality to aquatic invertebrates from acute exposures.
- Chronic risks to birds and mammals.
- Chronic risks identified for individual bees (larval and adult).
  - There is uncertainty due to a lack of LOAEL values in the toxicity studies available for adult and larval bees. We are requesting replacement chronic bee studies.
  - The Agency is asking for replacement adult and larval bee chronic toxicity studies to better address the chronic risks.

Proposed Mitigation in PID

- The following risk mitigation will reduce aggregate cancer risk:
  - Cancel residential uses to resolve risks to residential handlers and applicators. Little impact is expected on users from the mitigation.
  - Cancel use on bananas and revoke the tolerance. Little impact on users is expected as there are few bananas grown in the U.S.
  - Reduce application rate and/or number of applications for beans, berries, cacao, coffee, corn, cotton, forestry, soybean. Impacts on users are expected to be limited because the typical use rates are at or below the new proposed use rate and number of applications.
  - Require a banded application with boom height at 2 ft above the ground for orchards and grapes. This is already the most common application practice in the crops.
- The following will reduce occupational risks of concern to below the level of concern:
  - Cancel application with mechanically pressurized handguns.
  - Require sprays made with backpack sprayer for forestry and Christmas trees use be directed toward the ground. This is not expected to significantly impact these uses
  - Cancel hand dispersal of granules for Christmas trees use
- The following will reduce occupational risks and they are balanced with the benefits:
  - Require double layer of clothing plus gloves for all remaining backpack sprayer uses.
  - Require double layer of clothing, gloves and PF10 respirator for mixing/loading/applying liquids to landscaping (trees/shrubs/bushes) and nursery ornamentals.
- Require standard spray drift mitigation with coarse and coarser spray.
- Extend 25 ft vegetated filter strip requirement to all labels for use other than the Pacific Coast states. This is already on the most used oxyfluorfen labels.
- Increase REI to 2 days for handset irrigation for ornamentals and reduce maximum annual application rate to 2 lb/acre. This reduces risk to where it can be balanced with benefits. This is not expected to significantly impact this use.
- The registrant has agreed to all the dietary mitigation. They have been briefed on all the proposed mitigation for occupational risks and will respond in the comment period for the PID.

Communications

- No additional communication anticipated
- BEAD reached out to USDA with crop-specific questions to tailor mitigation to avoid substantial impacts on growers. Questions remain as to impacts on coffee and cacao production in Hawaii.

Pyrethrins: PBO; MGK-264 PID Abstract

Background

- Piperonyl butoxide (PBO), pyrethrins, and MGK-264: three separate PIDs scheduled for June FY21.
- Risk mitigation strategies for all three cases will have similarities given the similar use patterns and similar risks of concern.
- Pyrethrins: used as insecticide primarily in non-agricultural areas--residential households, landscaping, pet treatments, and commercial facilities. Agricultural uses include post-harvest fruit treatment, livestock treatment/premise treatments, and production of various fruits and vegetables for which pyrethrins have high benefits as an organic insecticide. Benefits are generally lower in non-agricultural use settings since there are many effective alternatives. While pyrethrins and pyrethroids both are used in canine flea and tick treatment, the use of pyrethrins to control fleas and ticks on cats may be associated with greater benefits because cats are very sensitive to the pyrethroids.
- PBO & MGK-264 are synergists/enhancers – often formulated w/pyrethrins and with some pyrethroids and neonicotinoids for agricultural use. Synergists are not allowed in organic agriculture. They greatly increase the efficacy of pyrethrins and some pyrethroids, thus allowing use at lower application rates. They are also useful for slowing development of resistance to such active ingredients. Both have high benefits in non-agricultural settings when formulated with pyrethroids.
- Pyrethrins + PBO are recommended and used for adult mosquito control. PBO is also used with permethrin, a pyrethroid, for adult mosquito control. The permethrin ID was completed in 2020.
- MGK-264: No crop uses. Outdoor uses are limited to building surfaces.

Key Points

- Based on human health risk assessments (2017, 2021), many residential and occupational scenarios fail due to inhalation risk (even with addition of PF10 respirators or engineering controls) and are candidates for product cancellation or restrictions on specific application methods or equipment.
- For pyrethrins and PBO, some crop tolerances/postharvest uses are not supported with residue data and are also candidates for cancellation.
- For MGK-264 and pyrethrins, EPA has required additional thyroid data and the absence of data from the comparative thyroid assay (CTA) results in the addition of a 10x database uncertainty factor, which contributes to the potential risks of concern associated with incidental oral exposure for a variety of residential uses. The CTA study submissions for pyrethrins and MGK-264 are expected in November 2021 and August 2021, respectively.
- Registrants are currently voluntarily developing *in vitro* inhalation data (for all three ais) that will not be received in time to be considered for the PIDs but could impact IDs. Data

for PBO and pyrethrins have recently been submitted and data for MGK-264 are expected soon. The registrants claim that the data may increase MOEs ~10-fold. If the Agency concurs, the data could help address many problematic exposure scenarios.

- IDs currently scheduled for Q1 2022. Timing will depend on the data submissions and whether they impact the mitigation proposals.

Human Health Risk Assessment Conclusions

- Potential residential and occupational handler and post-application short and intermediate term inhalation risks of concern (based on respiratory tract lesions for multiple use patterns [aerosols, dusts, liquid sprays, fog/mists])
- Residential post-application risks to children from incidental oral and dermal exposure.

Ecological Risk Assessment Conclusions

- For the pyrethrins and PBO, risks of concern were identified for aquatic invertebrates and fish from indoor, outdoor, and agricultural uses. Pyrethrins ecological risks of concern were addressed in the 2016 pyrethroids Ecological Risk Assessment (ERA) and 2019 Ecological Mitigation Proposal and include environmental hazards statements, runoff and spray drift mitigation measures, revised treatment parameters.
- Due to MGK-264's limited outdoor uses (applications only to building surfaces and spot treatments on structures) the likelihood of environmental exposures is low. There were small risk exceedances to freshwater fish and plants, but these risks are thought to be unlikely with MGK-264's use pattern.

Proposed Mitigation in PID

- Prohibit application via indoor dusters, shakers, aerosol space sprays, handheld/portable misters and foggers, several liquid spray applications for all three a.i.s.
- Increased personal protective equipment (respirators, gloves, respirators, and/or double layer clothing) for many occupational handler scenarios.
- Multiple use cancellations and/or modes of application prohibitions.
    - Residential use sites
    - Commercial use sites (e.g., food handling establishments, warehouses)
    - Indoor agricultural use sites (e.g., poultry houses, animal quarters)
    - Application methods proposed for prohibition include dusts, shaker cans, aerosol cans, backpacks, manually pressurized handgun/handwands, handheld/portable foggers, misting systems
- Mandatory spray drift management labeling (Pyrethrins & PBO).
- For pyrethrins, ecological mitigation the same as 2019 proposal for pyrethroids; PBO ecological risk mitigation includes water protection and runoff statements which are similar to the pyrethroids and pyrethrins. No ecological risk mitigation is needed for MGK-264.
- Low impacts on users are expected from eco risk mitigation and the addition of PPE. High impacts on users are expected from the potential use cancellations/application prohibitions for MGK-264 and PBO. Lower impacts expected for pyrethrins because there are alternative formulations/application methods available. The impacts on users will be fully assessed and considered for the ID, once the expected inhalation data are assessed and the risk mitigation is finalized.

Communications

- Significant public comments expected on all PIDs.
- OPP update and web updates anticipated.
- Ongoing conversations with Pyrethrins Joint Venture, PBO Task Force II, and MGK registrants.

Difenoconazole PID Summary

Release Proposed Interim Decision. Difenoconazole is a systemic broad-spectrum triazole fungicide registered for use as seed treatment on a number of cereal grain crops, cotton, canola, and potato seed pieces; as a foliar application to rice, fruits and nuts, vegetables, and field crops; and for post-harvest applications on some fruits and vegetables. Products containing difenoconazole are also registered for use on golf course turf and ornamental plants in commercial and residential landscaped areas. Difenoconazole is a demethylation inhibitor fungicide which acts by preventing development of fungal cell membranes in target pathogens giving it protective, curative, and eradicative properties against plant diseases. There are no human health risks of concern. There are potential ecological risks of concern for fish, aquatic invertebrates, birds, and mammals. Risks are considered low for honeybees and aquatic plants. Proposed mitigation includes a requirement that treated seeds be soil-incorporated to limit exposure to birds and mammals. Proposed label clarifications include restrictions for foliar rice uses in flooded fields, clarification of maximum annual application rates, advisory spray drift measures, surface and ground water advisories, a nontarget organism advisory, fungicide resistance management language, and updated glove language. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction* is minimal.

Fenbuconazole PID Summary

Release Proposed Interim Decision. Fenbuconazole is a triazole (conazole) fungicide currently registered for use on a variety of food and feed crops including cherry, orange, blueberries, almond, grapefruit, and apple. Fenbuconazole may be applied via ground and aerial equipment on all crops. In addition, it can be applied via chemigation on cranberries. Fenbuconazole has no registered residential or non-agricultural (including antimicrobial) uses. There are no human health risks of concern. There are potential ecological risks of concern for mammals (chronic), estuarine/marine fish (chronic, for cranberry use only), and terrestrial invertebrates (chronic for larval and adult). No mitigation is being proposed. Label clarifications include an update to the glove label statement, fungicide resistance management language, and the addition of advisory spray drift management language across all product labels. Little to no impacts to the current use patterns of fenbuconazole are expected from the proposed label updates. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is expected.

Isoxaflutole PID Summary

Release Proposed Interim Decision. Isoxaflutole is a is a preplant, preemergence, or postemergence HPPD inhibiting herbicide primarily used to control broadleaf weeds. Isoxaflutole is only registered for agricultural use and use sites include field corn, seed corn, corn grown for silage, and for isoxaflutole-resistant soybean (not commercially released yet). Isoxaflutole can only be used in 33 states and each label specifies the subset of states where use is permitted. It is applied via ground boom or incorporated into soil above the seed planting zone

and all products are restricted use. Dietary cancer risks estimates were originally of concern most of the risk was derived from drinking water exposure, but these were reassessed using a refined scenario and dietary cancer risk estimates with this scenario are no longer of concern. Ecological risks of concern were identified for terrestrial plants. The majority of isoxaflutole incidents involved damage to plants, and many of these incidents have occurred from direct application to corn (the target crop). Proposed label clarifications include mandatory spray drift language, updated herbicide resistance management statements, and updated gloves statements on all product labels. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction* is minimal.

Mesotrione PID Summary

Release Proposed Interim Decision. Mesotrione is a member of a group of systemic triketone compounds that inhibit the enzyme *p*-hydroxyphenyl pyruvate dioxygenase (HPPD). Mesotrione is registered for use as a pre-plant and post-emergence herbicide to control broadleaf weeds in agricultural and non-agricultural areas. Registered agricultural use sites for mesotrione include blueberries, caneberries, cranberries, rhubarb, popcorn, field corn, grass grown for seed, sod, sweet corn, okra, asparagus, millet, oats, sorghum, sugarcane, flax, and soybeans. Registered non-agricultural use sites for mesotrione include athletic fields, recreational areas, residential lawns, and golf courses. Mesotrione is applied via ground and aerial application equipment. There are no human health risks of concern identified. There are potential ecological risks of concern identified for mammals, terrestrial plants, and aquatic plants. Proposed label clarifications include mandatory spray drift measures, surface water and ground water advisories, a nontarget organism advisory, herbicide resistance management language, and updated glove language. Most usage is on corn; it plays an important role in managing glyphosate resistant weeds and slowing the development of glyphosate resistance. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction* is minimal.

Metaldehyde PID Summary

Release Proposed Interim Decision. Metaldehyde is a systemic molluscicide for controlling slugs and snails. Metaldehyde is registered for a variety of residential and agricultural use sites including (but not limited to) beans, citrus, corn, berries, leafy vegetables, grasses grown for seed, watercress, wheat, and soybean. Metaldehyde may also be used for state and federal mollusk eradication initiatives where application is permitted for wide area/general outdoor treatment. Metaldehyde is only applied via ground application and is formulated as pelleted granules or as a liquid. There is one aerial use of a pelleted formulation (Oregon SLN-OR110016) for Christmas tree plantations. The majority of metaldehyde applications are soil directed and there are limited use sites where foliar directed use is permitted. Available usage data between 2015 and 2019 shows that metaldehyde was used primarily on oranges with approximately 80,000 pounds applied on average annually (USDA NASS, 2020). There are no human health risks of concern. There are potential risks of concern for birds, mammals and domestic dogs. Risks to pollinators are unclear and a full suite of Tier I data is not available. Significant mitigation was implemented with the 2006 RED (amended in 2007) to reduce domestic dog incidents associated with residential products. While incidents have declined since the implementation of the RED mitigation, over 40 domestic dog incidents occurred between 2017 and 2019 and 18 of these incidents involved mortality. However, the end use product associated with the majority of incidents is no longer marketed/produced by the registrant.

Proposed label clarifications include updated personal protective equipment language, advisory resistance management language, and plant back intervals. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction* is minimal.

Tembotrione PID Summary

Release Proposed Interim Decision. Tembotrione is a member of a group of systemic triketone compounds that inhibit the enzyme *p*-hydroxyphenyl pyruvate dioxygenase (HPPD). Tembotrione is a pre-plant, pre-emergence, post-emergence, and/or post-harvest broad-spectrum herbicide registered for use on corn (field, sweet, pop) to control annual grasses and broadleaf weeds. Section 3 labels allow for application by ground equipment; however, several FIFRA Section 24(c) labels permit aerial applications as well. Tembotrione has no registered residential or non-agricultural (including antimicrobial) uses. There are no human health risks of concern. There are potential ecological risks of concern for mammals, aquatic invertebrates, aquatic and terrestrial plants. Proposed label clarifications include adding a maximum annual application rate to all labels that include any post-harvest applications to eliminate ambiguity as well as updating the glove statement, aquatic invertebrate environmental hazard statements, non-target organism advisory statement, herbicide resistance management language, and mandatory and advisory spray drift management language across all product labels. Little to no impacts are expected from the proposed label updates. *Anticipated stakeholder reaction*: Minimal stakeholder feedback is expected.

Topramezone PID Summary

Release Proposed Interim Decision. Topramezone is a broad-spectrum systemic herbicide registered for use to control broadleaf and certain grass weeds. The mode of action in plants is inhibition of the 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme. Topramezone can be applied by ground, air, hand-held spray equipment, backpack sprayers, hose-end sprayers, boat-mounted sprayers, and submerged aquatic hoses. Agricultural use sites include field corn (grown for grain, silage, or seed), popcorn (grown for ear, kernel, or seed), sweet corn (grown for ear, kernel, or seed), sod farms, and sugarcane. Non-agricultural use sites include aquatic vegetation, non-crop ornamentals, African marigolds for lutein and zeaxanthin production, residential and recreational turf grass, rights-of-way, and tree plantations. There are no human health risks of concern. There are potential risks of concern for estuarine/ marine invertebrates, mammals, vascular aquatic plants, terrestrial plants, and pollinators. Proposed label clarifications include updated mandatory spray drift language (including medium or coarser droplet size, 3 foot release height for ground applications, and 15 mph wind speed restrictions), advisory spray drift language, non-target organism advisory statement, groundwater and surface water advisory statements, clarification of maximum annual rates, and resistance management language. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction* is minimal.

B. FY2021 Q3 BPPD (Biopesticide Use) PID Summaries

Cinnamaldehyde PID Summary

Release Proposed Interim Decision (PID). Cinnamaldehyde is registered for use as a fungicide, insecticide, algaecide and miticide for agricultural crops, horticultural crops, and turf. Pesticide products containing cinnamaldehyde as an active ingredient are registered for use to control a

variety of pests including aphids, mites, leafhoppers, whiteflies (including silverleaf and greenhouse), thrips (including western flower), algae, moss, and liverworts/hornworts/pearlworts. Fungicidal cinnamaldehyde products are registered for use to control powdery mildew, rhizoctonia, pythium, dollar spot, and pitch canker disease. It is also registered as a microbicide for use in controlling bacteria in oil field processing, gas production, gas storage fields, water holding tanks, and fuel storage tanks. No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of cinnamaldehyde. *Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

Farnesol and Nerolidol PID Summary

Release combined Preliminary Work Plan and Proposed Interim Decision (PWP-PID) for the second cycle of registration review. Farnesol and nerolidol are naturally occurring sesquiterpene mite attractants that were originally isolated from essential oils found in plants such as rose, citronella, and lemongrass. These attractants are best described as parahormones, being most recently isolated from female mites. Pesticide products containing farnesol and nerolidol are registered for use in the control of mites on agricultural crops and ornamentals. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of the active ingredients in this case. *Anticipated stakeholder reaction*: minimal stakeholder reaction is anticipated.

***Nosema locustae* PID Summary**

Release combined Preliminary Work Plan and Proposed Interim Decision (PWP-PID) for the second cycle of registration review. *Nosema locustae* is a naturally occurring microorganism that infects the fat bodies of grasshoppers after consumption of the bait. It is registered for use to reduce/ control various grasshoppers and Mormon crickets. Pesticide products containing *Nosema locustae* are registered for use in residential and agricultural settings. No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. *Anticipated stakeholder reaction*: minimal stakeholder reaction is anticipated.

***Ulocladium oudemansii* (U3 Strain) PID Summary**

Release combined Preliminary Work Plan and Proposed Interim Decision (PWP-PID) for the second cycle of registration review. *Ulocladium oudemansii* (U3 Strain) is a naturally occurring soil fungus existing as a saprophyte of dead and decaying plant matter. As a pesticide it is used to protect fruit crops, vegetable crops and ornamental plants from certain plant pathogenic diseases by competing for the same ecological niches and nutrients. Pesticide products containing *Ulocladium oudemansii* (U3 Strain) are registered for agricultural use such as in outdoors, greenhouses, horticultural crops (food commodities), and ornamental plants (greenhouses and nurseries). No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of *Ulocladium oudemansii* (U3 Strain). *Anticipated stakeholder reaction*: minimal stakeholder reaction is anticipated.

4. Interim Decisions

The Interim Decisions (IDs) are the fourth step in the four-step process. In the ID, EPA requires mitigation measures to reduce the human health and ecological risks identified in step two, considering public comment on the Proposed Interim Decisions (PIDs) – step three. No proactive communications are planned for these procedural announcements. EPA will have subject matter experts assist with press inquiries should they come in.

A. FY2021 Q3 AD (Antimicrobial Use) ID Abstracts and Summaries

Halohydantoins ID Abstract

Current Status

- Halohydantoins are registered for use for microbial control in water and water systems (disinfectant in pools, spas, hot tubs; sanitizer for hard surfaces, toilet bowls; bacterial and fungal control in industrial water systems; egg washing, fruit/vegetable washing and drinking water disinfection).
- There are eight active ingredients and 90 active product registrations.
    - Five of these active ingredients contain bromine (PC codes 006315, 006317, 006322, 006333, 128989)

Key Points

- Halohydantoin active ingredients that contain bromine have the potential to break down into bromate under UV radiation.
- The halohydantoins DRA was completed without assessing bromate formation in outdoor swimming pools, hot tubs, and spas.
- The halohydantoins ID incorporates findings made in the inorganic halides DRA, which has the same potential for bromate formation. Risk estimates for the inorganic halides are protective for the halohydantoins.
    - Post-application risk of concern was identified for swimmers due to the formation of bromate.
        - An acceptable bromate formation study was not received by the Agency for use in risk assessment. In lieu of this data, the Agency conducted a conservative analysis of risk for bromate formation in swimming pools using current inorganic halide product labels. Since complete conversion to bromate is unlikely, and the actual amount of conversion is unknown, the bromate water concentration in swimming pool water corresponding to a cancer risk of 1.0 x 10-6 was back calculated. Based on these back calculations, bromate water concentrations of 5 µg/liter and 18 µg/liter for competitive and recreational swimmers, respectively, correspond to a cancer risk of 1 x 10-6.
    - No post-application risks of concern were identified for hot tubs or spas
        - Bromate ion is formed under UV exposure. The spa and hot tub exposure scenario differs from the pool use scenario because spa and hot tub users are expected to generally keep their heads above the water line, the amount of water ingested by spa and hot tub users from movements like splashing is expected to be negligible, and the frequency of exposures

would be minimal as compared to the swimmer scenario. In addition, hot tubs and spas are generally covered when not in use and UV light is needed to form bromate.

- Because of identical concerns with inorganic halides, the halohydantoins ID is being updated to align with inorganic halides findings and mitigation measures concerning outdoor pools, spas, and hot tubs.
- Alternative treatments for swimming pools include salt chlorine generators (which are already used in almost 70% of swimming pools), chloroisocyanurates, lithium hypochlorite (LiClO) and calcium hypochlorite.

Mitigation Changes Between PID and ID

- No mitigation was proposed at the time of the PID.
- The outdoor pool use is being cancelled for halohydantoin products whose active ingredients contain bromine. Indoor pools are unaffected.
- Language is being added to hot tub and spa products to advise end users that hot tubs and spas must be covered when not in use. This is precautionary language as there were no risks identified with this use.
- For both mitigation measures, the registrants who will be impacted by these measures have been contacted and are aware of the Agency's proposal. Those who have offered feedback were in agreement with this strategy.

Communications

None planned at this time

10,10'-Oxybisphenoxarsine (OBPA) ID Summary

Release Interim Decision (ID). OBPA is used as a fungicide, disinfectant, bacteriostat, microbicide, microbiostat, and fungistat. There are various uses of OBPA in industrial adhesives, resin/latex polymer emulsions, specialty industrial products, textiles/textile fiber/cordage (not for clothing), flexible vinyl systems, preservative in plastic products (not for toys), coatings, floor and wall coverings, coated fabrics for upholstery, shower curtains, mattress covers, ink, and latex. The human health risk assessment identified risks of concern for dermal and oral exposures from post-application residential scenarios for PVC flooring, carpets, and treated mattress covers. Risks are not expected to nontarget aquatic or terrestrial organisms based on limited routes of exposure. AD is making a "no effects" determination for Federally listed species and their designated critical habitats. To mitigate post-application residential risks, the registrant has agreed to amend their labels to provide more specificity in how the products are used. Required label amendments include the removal of the mattress cover use and restrictions on the type of textiles that can contain OBPA. *Anticipated stakeholder reaction*: Minimal stakeholder feedback is anticipated due to the mitigation measures being proposed by EPA.

Citric acid ID Summary

Release Interim Decision (ID). Citric acid is an antimicrobial pesticide used as a disinfectant, sanitizer, bactericide, fungicide/fungistat, and virucide for hard non-porous surfaces included in many products for use in residential and public access premises (e.g., kitchen counter tops, bathroom shower stalls, toilets, utensils, kitchen cutting boards, diaper pails, changing tables, garbage cans, pet areas, cafeterias and doctor's offices) and in fruit and vegetable washes for use

as a disinfectant, sanitizer, virucide, and germicide. Citric acid is registered in multiple end-use products and is both a food-contact and non-food contact use chemical. In addition, there are over 700 registered products containing citric acid as an inert ingredient. Citric acid is additionally registered for use as a non-selective herbicide. No environmental or human health data are required, no further risk assessments are needed, and no label amendments on citric acid products are needed at this time. A "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has been made. The Agency is preparing an endocrine disrupter screening program (EDSP) exemption for citric acid. Once this exemption is signed, the Agency will make a final decision. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is expected.

Polixetonium Chloride (Busan 77) ID Summary

Release Interim Decision (ID). Polixetonium chloride, the active ingredient in Busan 77, is an algaecide, bacteriostat, fungicide, microbiocide/microbiostat and molluscicide. Products containing polixetonium chloride are registered for use in swimming pools, spas, whirlpools, hot tubs, metal working fluids, fire water protection systems, cooling water towers, petroleum secondary recovery systems, paper mill process water, air washer water systems, and ornamental ponds. The Agency calculated an MOE of 3.6 (LOC 10) for residential handlers applying polixetonium chloride products to pools at the winterizing use rate, which occurs once per year at a concentration of 10 ppm. Despite this risk of concern, the Agency views this exposure as having limited risk because pools are only winterized once per year and the MOE is based on a 90-day dermal toxicity study where irritation effects did not occur until day 9 of the study. Risks of concern were identified for occupational handlers as a result of post-application dermal exposure when using metalworking fluids (MWFs). Ecological risks were identified for non-target aquatic organisms resulting from the cooling tower and pulp and papermill uses. The mitigation strategy for the MWF use is to require that polixetonium chloride products only be applied to MWFs in enclosed and automated systems. The mitigation for the ecological risks of concern is to require that registrants include label language requiring an exposure reduction plan for cooling tower and pulp and paper mill uses and specifying that application rates depend on the extent of contamination and product concentration in treated water. *Anticipated stakeholder reaction*: Minimal stakeholder feedback is anticipated.

B. FY2021 Q3 PRD (Conventional Use) ID Abstracts and Summaries

Coumaphos ID Abstract

Current Status

- The first pesticide product containing coumaphos was registered in the U.S. in 1958.
- Coumaphos is a member of the organophosphate (OP) insecticide class and primarily affects the nervous system through cholinesterase (ChE) inhibition.
- Registered for control of arthropod pests on beef and dairy cattle, goats, horses, sheep and swine by spray, dip, and dust applied directly to the animal or its bedding, as a treated strip in bee hives, and cattle ear tags.
- Coumaphos is especially important in the USDA Animal and Plant Health Inspection Service (APHIS) Cattle Fever Tick Eradication Program (CFTEP).
    - There are very few alternative treatments and all alternatives have limited success.

Key Points

- OCSPP IO Briefing May 4, 2021.
- Since the 2018 PID was published, APHIS and Bayer informed OCSPP of:
  - Potential misuse by USDA APHIS CFTEP (e.g., PPE, product misuse, accusations of improper disposal).
  - A lawsuit between cattle ranchers in Texas and USDA over cattle deaths allegedly caused by coumaphos use within the program.
  - Several application methods identified by USDA and Bayer Animal Health that were not originally evaluated in the risk assessments (e.g., spray-box and vehicle-mounted sprayer uses).
  - OCSPP also received comments on the 2018 PID about the need to retain horse uses.
- Due to these issues, a Revised PID was published in 2020. Since the Revised PID was published, EPA has met with USDA, EAH (formerly Bayer Animal Health), and representatives from the State of Texas to discuss the proposed mitigation.
  - USDA has continued to request revisions to the statement "do not spray in a confined, non-ventilated area."
  - Spray-dip boxes have been modified since the 2018 lawsuit by addition of small ventilation ports on boxes.
    - Modifications were made so that spray-dip boxes would no longer be "confined, non-ventilated" spaces; however, the Agency does not have data to indicate whether the boxes are ventilated, nor do we know the original intent of the statement (whether it applies to humans, animals, or both). For these reasons, the Agency does not intend to move this statement. We reiterated this to APHIS in a meeting last week.

Proposed Mitigation in the Revised PID and Changes between the Revised PID and ID

- Between the Revised PID and ID, EPA determined it necessary to expand the use of vehicle mounted sprayers to include smaller operations (<100 cattle) so as not to unfairly burden small operations with mitigation.
- Other, unchanged mitigation measures include:
- Requirements of additional personal protective equipment and application restrictions
- Improvements to the label content regarding application rates and methods and directions for spray applications to address occupational handler risks of concern.

Stakeholder Reaction and Communications

- OCSPP received comments from:
  - The technical registrant, Elanco Animal Health and a private party on the importance and benefits of coumaphos as a pest control tool and alternative to pyrethroids;
  - Cascabel Cattle Company and a private party on USDA-APHIS' coumaphos use and incidents involving products containing coumaphos; and
  - USDA, Texas Department of Agriculture and USDA/ Texas Animal Health Commission on USDA-APHIS' coumaphos use, ventilation in spray-dip boxes, the mitigation proposed for vehicle-mounted sprayers, and label language changes.

- PRD and OGC have previously told USDA that label changes they requested (movement of "confined, non-ventilated statement) are not warranted based on scientific and historical evidence. EPA AA concurred with this decision in an AA briefing. We confirmed this in a subsequent meeting with APHIS and indicated we would review data they might provide to show that spray boxes are now ventilated.
- EPA may issue an internal desk statement.

Paraquat Dichloride ID Abstract

Current Status

- Paraquat dichloride is a fast-acting, non-selective herbicide used for the control of broadleaf and grass weeds in agricultural and non-agricultural use sites. It is a contact herbicide that desiccates and destroys plant cell membranes within hours of application.
- Paraquat is a restricted use pesticide that can only be used by certified applicators and there are no paraquat products registered for homeowner or residential use.
- Paraquat is extremely toxic and as little as 1.5 teaspoons can be fatal if ingested.
- In 2016, EPA amended paraquat registrations to impose several additional restrictions intended to prevent accidental ingestion incidents. All requirements from this human health mitigation were implemented on labels by December 30, 2020.
- ID scheduled for June 2021.

Key Points

- OCSPP IO Briefing May 18, 2021.
- Paraquat is one of the most widely used herbicides in the U.S., with an average of 9 million pounds applied annually to over 17 million acres between 2015 and 2019. The crops with the highest number of acres treated are cotton, soybeans, and corn.
- There are a limited number of alternatives to paraquat.
- Human health and ecological risks of concern were identified for numerous use scenarios.
- Very high benefit/very high risk.

DRA Human Health Conclusions

- Occupational handler risks of concern for most scenarios, including for mixers, loaders and applicators.
- Occupational post-application risks of concern for cotton and alfalfa.
- Bystander risks are of concern up to 150 feet beyond the field edge for aerial applications.
- Weight of evidence from systematic review of paraquat open literature is insufficient to link paraquat exposure from pesticidal use of U.S. registered products to Parkinson's disease in humans.

DRA Ecological Risk Conclusions

- Potential acute and chronic risks to mammals and birds.
- Potential acute risks to adult honeybees.
- Potential risks to terrestrial plants.
- No potential risks to aquatic taxa, except for algae and benthic species (but bioavailability may be limited).

Proposed Mitigation in PID and Changes Between PID and ID

- New worker exposure data generated by the Agricultural Handler Exposure Task Force (AHETF) on closed loading systems resulted in updated dermal and inhalation risk estimates for mixing/loading exposure scenarios. There are no longer any risks of concern to occupational handlers for typical-acreage aerial applications (up to 350 acres per applicator per day).
- Based on this updated risk picture, instead of prohibiting aerial applications for all uses except cotton desiccation, EPA is limiting aerial applications to a maximum of 350 acres per applicator per 24-hour period for all uses except cotton desiccation. There is no acreage limit for the treatment of cotton for desiccation purposes.
- Residential spray drift buffers will also be required for all aerial applications, in order to mitigate residential bystander risk.

Communications – OPP update, internal Qs & As

Propylene Oxide (PPO) ID Abstract

Current Status

- First registered in 1982.
- Propylene oxide (PPO) is an insecticidal and sterilant fumigant pesticide with both conventional and antimicrobial uses, including to prevent *Salmonella* contamination in dried commodities. It is stored in pressurized cylinders released as a gas into a sealed chamber containing commodities to be treated.
    - Insecticidal use
        - Applied to commodities in vacuum-sealed and non-vacuum-sealed chambers (*e.g.*, shipping containers, box cars, and under tents or tarps in warehouses).
        - 8% PPO/92% CO_2 mixture.
    - Sterilant use:
        - Applied in vacuum-sealed chambers at full strength (100% PPO).
    - Registered use sites (includes both conventional and antimicrobial registrations).
        - Post-harvest food commodities, including include dried herbs, spices, onion, garlic, cacao, fruits, and nuts, as well as animal feed.
        - Non-food commodities, including pharmaceutical materials and empty shipping containers.
- The PID and DRAs were released together in October of 2020 for a sixty-day comment period, which was later extended for an additional thirty days. The Agency received ten public comments on these documents. Based on the comments, EPA revised its requirements for scrubbers, buffer zones and post fumigation intervals.

Key Points

- Commodity fumigants, like PPO, are high risk/high benefit active ingredients with critical applications in agriculture, trade and other industries. There are often no alternatives to these active ingredients for their registered uses, including the use on *Salmonella* in tree nuts and herbs and spices.
- In the PID, EPA proposed fumigation management plans (FMPs) and buffer zone requirements to protect workers and bystanders from exposure.

    - FMPs describe how and when a fumigant will be applied, include plans to respond to leaks or accidents, specify storage guidelines, and outline other protective measures such as active monitoring of fumigant air concentrations.
    - A buffer zone is a radius around an application site that personnel and non-occupational bystanders may enter only if wearing personnel protective equipment (PPE) during application and aeration times. Buffer zones are calculated on site depending on chamber size, application rate, stack height and configuration, and other factors, and may range in size from zero to 200 feet from the application chamber.
- Limited environmental risk is expected from registered uses of PPO because of its high volatility.
    - Potential risks of concern were identified in one modeling scenario (5 foot exhaust stack and 1 air change per hour) for mammals near to treatment sites.
- Additional data are needed to support tolerances for nutmeats. EPA proposed revocation of these tolerances in the PID, but in its comments, the registrant asked EPA to maintain tolerances.

Proposed Mitigation in PID and Changes Between PID and ID

- EPA finalized the buffer zone requirements to include specific distances (the proposed requirements did not include specific buffer zone sizes) and exemptions to buffer zone requirements if certain ventilation stack heights and aeration rate minimums are met.
- Mitigation proposed for conventional uses is anticipated to be protective of risks posed by antimicrobial uses, as microbial spoilage control is imparted during use of conventional products; there are no separately registered antimicrobial products.
- In the ID, the Agency will require labels to carry a minimum post-fumigation interval (PFI; a "hold time" before shipping, after fumigation) for nut meats. EPA had asked the registrant to propose such a PFI in the PID, which it did in its public comments, with supporting evidence.

Communications

- None planned.

Acetochlor ID Summary

Release Interim Decision. Acetochlor is a pre-plant, pre-emergence, and post-emergence herbicide registered for use on corn, alfalfa, cotton, peanuts, sorghum, soybeans, sugar beet and non-food perennial bioenergy crops. Acetochlor products are formulated as emulsifiable concentrate (EC), liquid, granule, and microencapsulate (ME). Acetochlor products can be applied via soil incorporation, aerial, broadcast, band sprayer, ground and chemigation equipment. The EC, liquid, and ME formulations can be applied by dry bulk fertilizer impregnation. There are no human health risks of concern. There are potential ecological risks of concern for freshwater invertebrates, aquatic plants, birds, mammals, terrestrial plants, and terrestrial invertebrates. Risk mitigation measures include mandatory and advisory spray drift language; updated surface water and groundwater advisory statements; non-target organism advisory; and herbicide resistance management. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is anticipated.

Dimethenamid/dimethenamid-p ID Summary

Release Interim Decision. Dimethenamid and dimethenamid-p are herbicides that control weed seedlings before they emerge, registered for a variety of field crops. Dimethenamid-p (only) is also used on major non-agricultural uses including landscape and grounds maintenance areas, tree plantations, turfgrass areas, golf courses, ornamental gardens, commercial ornamental production sites and grass grown for seed. The Agency identified potential risks of concern for mixer/loaders impregnating fertilizer into dimethenamid formulations. However, based on comments received during the PID comment period EPA updated this fertilizer scenario based on new exposure data, resulting in no human health risks of concern from this use. Potential ecological risks of concern were identified for honeybees (on- and off-field). The Agency is not requiring higher tier pollinator data at this time. Required label changes include standardizing advisory spray drift, glove requirement, and resistance management language. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is anticipated.

Fenamidone ID Summary

Release Interim Decision. Fenamidone is a broad-spectrum fungicide registered for control of certain pathogenic fungal diseases in a variety of crops, including but not limited to potatoes, root vegetables, grapes, ornamentals, and leafy vegetables. There are no human health risks of concern. There are potential chronic ecological risks of concern for fish and terrestrial invertebrates. The Agency is requiring updated spray drift management and updated advisory statements. Human health mitigation proposed in the PID to address occupational risks is no longer necessary due to changes to the toxicity endpoints prompted by public comments. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is anticipated.

Fenazaquin ID Summary

Release Interim Decision and addendum to the human health draft risk assessment. Fenazaquin is an insecticide, miticide, and fungicide for agricultural and non-agricultural uses that is registered for use on a variety of ornamental plants and fruit and nut trees. There are no human health risks of concern for fenazaquin, and the human health risk assessment addendum incorporates the recent registration action approving aerial application, which is not expected to impact risk conclusions. Uses of fenazaquin exceeded the LOCs for aquatic animals, piscivorus birds, mammals, and terrestrial invertebrates, and assessments identified uncertainties along with potential for risks to birds and mammals. The Agency is requiring higher tier pollinator data as a separate action. Required label changes include standardizing advisory spray drift, glove requirement, and resistance management language. *Anticipated stakeholder reaction:* Minimal stakeholder feedback is anticipated.

Myclobutanil ID Summary

Release Interim Decision. Myclobutanil is a systemic fungicide in the conazole class, first registered in 1984. There are a large variety of agricultural uses including field crops, row crops, orchard, and vineyard crops. There are also ornamental, forestry, and residential/commercial turf uses. The Agency identified potential inhalation and dermal human health risks of concern for occupational handlers under certain scenarios along with residential post-application risks of concern for liquid formulations. Risk mitigation measures include cancellation of use for turf, cotton seed treatment, and cancellation of a single dust formulation product. For occupational handler risks, the Agency is also requiring a 24-hour re-entry interval (REI) and increasing the

level of personal protection equipment (PPE) for certain activities. The Agency also identified potential ecological risks of concern for fish, aquatic invertebrates, aquatic and terrestrial plants, mammals, and bees. Risk mitigation measures include requiring mandatory and advisory spray drift mitigation measures and standardizing environmental hazard and advisory statements across labels. *Anticipated stakeholder reaction: Minimal stakeholder feedback is expected.*

C. FY2021 Q3 BPPD (Biopesticide Use) ID Summary

Insect Viruses ID Summary

Release Interim Decision. Pesticide products containing insect viruses are registered for insecticidal use against specific insects (e.g., gypsy moth, beet armyworm and the codling moth) in agricultural, forestry, and residential settings, as well as in food/feed processing, packing and storage areas. The insect viruses in this registration review case belong to the family Baculoviridae which presently consists of two genera, Nucleopolyhedrovirus (NPVs) and Granulovirus (GVs). Baculoviruses are obligate parasites of insects and closely related species. No human health or ecological risks were identified. No mitigation or labeling changes are needed for the registration review of insect viruses. *Anticipated stakeholder reaction*: minimal stakeholder reaction is anticipated.